

**UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION**

WAVE NEUROSCIENCE, INC. a Delaware
Corporation,

Plaintiff,

vs.

BRAIN FREQUENCY LLC, a Texas Limited
Liability Company

Defendant.

Case No. 5:23-CV-00626-XR

Honorable: Xavier Rodriguez

**PLAINTIFF WAVE NEUROSCIENCE,
INC.'S OPPOSITION TO DEFENDANT
BRAIN FREQUENCY, LLC'S MOTION
FOR PARTIAL SUMMARY JUDGMENT
PURSUANT TO THE PHYSICIAN'S
IMMUNITY STATUTE**

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TABLE OF CONTENTS

	<u>PAGE(S)</u>
I. INTRODUCTION	1
II. STATEMENT OF FACTS	2
III. LEGAL STANDARD ON SUMMARY JUDGMENT	4
IV. ARGUMENT	5
A. Brain Frequency Does Not Challenge Wave’s Device Claims	5
B. Brain Frequency is not a “Related Healthcare Entity”	6
1. Brain Frequency’s software license agreements do not meet the definition of a “related healthcare entity”	7
2. Brain Frequency is not a medical facility	9
C. Brain Frequency’s Infringement of the Asserted Method Claims Includes its Commercialization of a Regulated Medical Device	11
V. IN THE ALTERNATIVE, WAVE REQUESTS ADDITIONAL TIME TO CONDUCT DISCOVERY	14
VI. CONCLUSION	15

TABLE OF AUTHORITIES**PAGE(S)****Federal Cases**

<i>Boudreaux v. Swift Transp. Co.</i> , 402 F.3d 536 (5th Cir. 2005)	6
<i>Celotex Corp. v. Catrett</i> , 477 U.S. 317 (1986).....	6
<i>DIRECTV, Inc. v. Robson</i> , 420 F.3d 532 (5th Cir. 2005)	6
<i>Emtel, Inc. v. Lipidlabs, Inc.</i> , 583 F. Supp. 2d 811 (S.D. Tex. 2008)	<i>passim</i>
<i>Lamson v. United States</i> , 117 Fed. Cl. 755 (2014)	<i>passim</i>
<i>Lincoln Gen. Ins. Co. v. Reyna</i> , 401 F.3d 347 (5th Cir. 2005)	5
<i>Quorum Health Res., L.L.C. v. Maverick County Hosp. Dist.</i> , 308 F.3d 451 (5th Cir. 2002)	6
<i>Stearns Airport Equip. Co. v. FMC Corp.</i> , 170 F.3d 518 (5th Cir.1999)	19
<i>Viveve, Inc. v. Thermigen, LLC</i> , No. 2:16-CV-1189-JRG, 2017 WL 1425604 (E.D. Tex. Apr. 20, 2017)	17
<i>Wash. State Dept. of Soc. and Health Servs. v. Guardianship Estate of Keffeler</i> , 537 U.S. 371 (2003).....	12
<i>Wichita Falls Off. Assocs. v. Banc One Corp.</i> , 978 F.2d 915 (5th Cir. 1992)	18

Federal Statutes

35 U.S.C. § 287(c)	<i>passim</i>
35 U.S.C. § 287(c) (1).....	6
35 U.S.C. § 287(c)(2)(C)	7, 8, 12
35 U.S.C. § 287(c)(3).....	2, 14, 15, 18

Rules

Fed. R. Civ. P. 56.....	18
Fed. R. Civ. P. 56(c)	5
Fed. R. Civ. P. 56(d)	18, 19
Fed. R. Civ. P. 56(e)	2
Fed. R. Civ. P. 56(f).....	19

Other Authorities

Federal Food, Drug, and Cosmetic Act	4, 16, 18
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I. INTRODUCTION

Defendant Brain Frequency, LLC’s Motion for Partial Summary Judgment (“Motion”) does not attempt to argue Brain Frequency does not infringe Plaintiff Wave Neuroscience, Inc.’s patents. Nor could it.

Instead, Brain Frequency attempts to apply a rarely litigated section of the Patent Act known as the “Physician’s Immunity Statute.” 35 U.S.C. § 287(c). Section 287 is intended to protect doctors and the facilities at which they perform their services from patent infringement in specified circumstances. But, Brain Frequency is not a medical provider, nor is it a facility at which medical providers practice medicine. Nevertheless, Brain Frequency attempts to avoid liability for its actions by claiming that *solely* because it licenses its technology to medical providers, it has a “professional affiliation” with its licensees and is therefore a “related healthcare entity.” This analysis is overly simplistic and wrong.

The facts, including Brain Frequency’s admissions that it only licenses software in exchange for a license fee, and that it does not provide any medical advice, diagnosis, or medical treatment, preclude any finding that Brain Frequency is a “related healthcare entity” subject to immunity for patent infringement under the “Physician’s Immunity Statute,” 35 U.S.C. § 287(c).

As a second and separate reason Brain Frequency cannot claim immunity, Brain Frequency admits that the “Brain Frequency System” it commercializes requires a TMS treatment device to operate. Brain Frequency offers those TMS devices for lease directly to its customers. And, those TMS devices are regulated by the FDA. As a result, Brain Frequency falls squarely within the exemption written directly into Section 287(c) for commercial use or sale of a regulated medical device. 35 U.S.C. § 287(c)(3). Thus, the Court should deny Brain Frequency’s Motion for Partial Summary Judgment.

II. STATEMENT OF FACTS¹

Brain Frequency's sole business is the licensing of software in exchange for money. Doc. 30-3 (Manish Decl.) ¶ 4 (Brain Frequency provides software technology...); ¶ 6 ("Brain Frequency license the Brain Frequency Software to a total of five individual medical practitioners..."). The medical providers, *not* Brain Frequency, provide the medical treatments. *Id.* ¶ 8 ("Each of Brain Frequency's medical practitioner licensees provide medical diagnosis or treatment..."); ¶ 10 ("Brain Frequency only provides software to assist in the facilitation of treatments..."); Doc. No. 30-8² at 1 (usage fee), *id.* at 3 (§ 1.5 defining "Fees"); *id.* at 6-7 (§ 5 "Fees, Invoicing and Payment").

Brain Frequency does not provide medical advice, diagnoses, or medical treatment. This is proclaimed, twice, in all capital letters in its customer contracts:

NEITHER BRAIN FREQUENCY NOR THE BRAIN FREQUENCY SYSTEM PROVIDES MEDICAL ADVICE, INSTRUCTION FOR DIAGNOSIS OF A MEDICAL CONDITION, OR INSTRUCTION FOR TREATMENT OF A MEDICAL CONDITION.

Doc. 30-8 at 1, 10 (emphasis original).³

Brain Frequency's "Brain Frequency System" (which Wave accuses of infringing the asserted patents) *requires* the use of a "Brain Frequency approved" TMS device. Doc. 30-8 at 4 (exemplar license agreement § 2.2 Conditions of Use require "Licensee must acquire the

¹ Brain Frequency identifies 63 purported "undisputed facts" in support of its Motion. Doc. No. 30-1. Wave expressly disputes only those material facts necessary to demonstrate that Brain Frequency cannot prevail on summary judgment (specifically, the "facts" identified in paragraphs 47, 50-52, 54, 57-63). Wave's election not to dispute Brain Frequency's other "facts" is not an admission as to the truth or disputed nature of those facts. Fed. R. Civ. Proc. 56(e); Advisory Committee Note to 2010 Amendment ("[t]he fact is considered undisputed only for purposes of the motion").

² Exemplar "Brain Frequency System License and Services Agreement", Exhibit 5 to Manish Decl. *See* Doc. 30-8 (Manish Decl.) ¶ 7.

³ Nor could it. Brain Frequency's founder, Shannon Malish, is not a doctor. Doc. No. 30-3 ¶ 2. Brain Frequency does not claim to employ any doctors. *See generally*, Doc. No. 30-3.

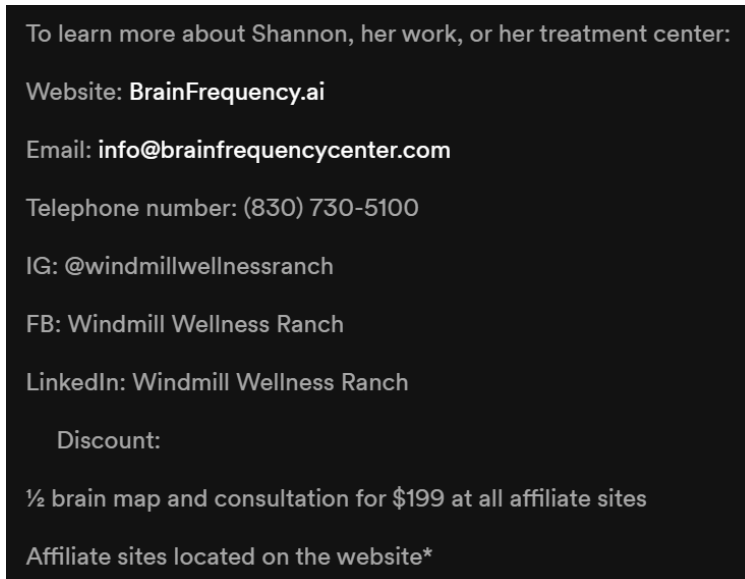
equipment listed on Schedule 2 for the operation of the Brain Frequency System.”); *id.* at 14 (Schedule 2 listing “Brain Frequency approved TMS Treatment Machine[s]”).

Brain Frequency leases its “approved” TMS devices to its customers. Doc. 30-8 at 1 (§ 1.7 defining “Lease Fees” as “the fees for lease of any equipment that may be set forth in Schedule 2”); *id.* at 4 (§ 2.2.2 “If Schedule 2 states that Licensee will lease the equipment from Brain Frequency, then the terms of this Agreement will apply to such lease.”); *id.* at 5 (§ 4.3 “Licensee shall properly handle and maintain all equipment that Licensee leases from Brain Frequency.”); *id.* at 7 (§ 5.13 “Lease Fees will be due prior to the start of the applicable lease period.”); *id.* at 8 (§ 6.3 upon termination (“Licensee shall return to Brain Frequency all equipment that it has leased from Brain Frequency”).

The “approved” TMS devices required by Brain Frequency for its software to function are regulated under the Federal Food, Drug, and Cosmetic Act. Doc. No. 30-8 (MagVenture MagPro R30-PR TMS device listed as only “Brain Frequency approved TMS Treatment Machine”); Request for Judicial Notice (“RJN”), Exs. A-H (Summaries and Premarket approvals for MagVenture R30 devices identifying regulation by U.S. Food and Drug Administration under Federal Food, Drug and Cosmetic Act).

Lastly, there can be no dispute that Brain Frequency is engaged in these activities for the commercial development or sale of its “System,” including the required use of a TMS device. Brain Frequency charges fees to its customers to license its software (*see* Doc. No. 30-8 at 6-7 (§ 5)), and has promoted the use of its software by advertising discounts on behalf of affiliated sites. As an example, in the same podcast referred to in Brain Frequency’s Motion (that was referenced in Wave’s second amended complaint (Doc. No. 10 at ¶ 35)), which is available on Spotify, Spotify promotes an offered discount on treatment for podcast listeners “at all affiliate

sites” that are “located on the website” BrainFrequency.ai.⁴ Declaration of Deborah Mallgrave (“Mallgrave Decl.”) ¶ 3, Ex. I. That discount offer remains available to this day:



<https://open.spotify.com/episode/1tYFdD61I7dN4nvD7YrKKK?si=ef34fadb30054a80&nd=1&dlsi=069aab8dd96a4b38> (last visited May 17, 2024).

III. LEGAL STANDARD ON SUMMARY JUDGMENT

Summary judgment is appropriate if no genuine issue of material fact exists and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). “The movant bears the burden of identifying those portions of the record it believes demonstrate the absence of a genuine issue of material fact.” *Lincoln Gen. Ins. Co. v. Reyna*, 401 F.3d 347, 349 (5th Cir. 2005) (citing *Celotex Corp. v. Catrett*, 477 U.S. 317, 322–325 (1986)). If the burden of proof at

⁴ The referenced podcast is the Gladden Longevity Podcast, with the episode titled “Is this how you fix your brain once and for all?” from November 2022, available at <https://open.spotify.com/episode/1tYFdD61I7dN4nvD7YrKKK?si=ef34fadb30054a80&nd=1&dlsi=069aab8dd96a4b38>. In the podcast, Ms. Malish explains the development of and treatment of patients using Brain Frequency’s techniques. Not coincidentally, the host of the Gladden Longevity Podcast, Dr. Jeffrey Gladden, and his company, Gladden Longevity, are customers of Brain Frequency featured prominently on Brain Frequency’s website. Mallgrave Decl. ¶ 4; <https://brainfrequency.ai/texas> (last visited May 17, 2024).

trial lies with the nonmoving party, the movant may satisfy its initial burden by “‘showing’—that is, pointing out to the district court—that there is an absence of evidence to support the nonmoving party’s case.” *See Celotex*, 477 U.S. at 325. Although the party moving for summary judgment must demonstrate the absence of a genuine issue of material fact, it does not need to negate the elements of the nonmovant’s case. *Boudreaux v. Swift Transp. Co.*, 402 F.3d 536, 540 (5th Cir. 2005) (citation omitted). “‘An issue is material if its resolution could affect the outcome of the action.’” *DIRECTV, Inc. v. Robson*, 420 F.3d 532, 536 (5th Cir. 2005) (quoting *Weeks Marine, Inc. v. Fireman's Fund Ins. Co.*, 340 F.3d 233, 235 (5th Cir.2003)). “If the moving party fails to meet its initial burden, the motion for summary judgment must be denied, regardless of the nonmovant’s response.” *Quorum Health Res., L.L.C. v. Maverick County Hosp. Dist.*, 308 F.3d 451, 471 (5th Cir. 2002) (citing *Little v. Liquid Air Corp.*, 37 F.3d 1069, 1075 (5th Cir. 1994) (en banc)).

IV. ARGUMENT

Brain Frequency seeks summary judgment on a rarely litigated area of law, the so-called “physician’s immunity” under 35 U.S.C. § 287(c). *Emtel, Inc. v. Lipidlabs, Inc.*, 583 F. Supp. 2d 811, 814 (S.D. Tex. 2008) (“This suit raises an issue rarely addressed in the case law: the application of the medical immunity provision of 35 U.S.C. § 287(c) (1).”); *see also Lamson v. United States*, 117 Fed. Cl. 755, 760 n.4 (2014) (“To date, there has been only one other decision interpreting § 287(c).”)

A. Brain Frequency Does Not Challenge Wave’s Device Claims

A medical practitioner’s immunity from suit under Section 287(c) is not unlimited. That statutory immunity *only* applies “[w]ith respect to a medical practitioner’s performance of a medical activity” and specifically excludes the practitioner’s “use of a patented machine.” 35

U.S.C. § 287(c). While, as set forth fully below, Wave properly alleges that Brain Frequency is not a “related healthcare entity” as that term is defined in Section 287(c), that distinction is irrelevant for purposes of the device claims in the ’354 Patent. A “related healthcare entity” is only entitled to immunity based on a relationship in which the medial provider performs a “medical activity.” 35 U.S.C. § 287(c)(2)(C). Since the use of a patented medical device is specifically excluded from protection as a “medical activity,” Brain Frequency cannot be immune from device claims.

Recognizing this, Brain Frequency moves only for partial summary judgment on the asserted method claims, but does not seek summary judgment as to Wave’s device claims. Doc. 30 at 4 n.2.

B. Brain Frequency is not a “Related Healthcare Entity”

As to Wave’s asserted method claims, “[t]he plain language of § 287(c) states that “the provisions of sections 281, 283, 284, and 285 shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity.” 35 U.S.C. § 287(c). Thus, the provision immunizes the practitioner and *the institutions they work for* from all liability for infringement in connection with medical treatment.” *Lamson*, 117 Fed. Cl. at 762 (emphasis added).

As defined by the statute, the term “related healthcare entity” means “an entity with which a medical practitioner has a professional affiliation under which the medical practitioner performs the medical activity, including but not limited to a nursing home, hospital, university, medical school, health maintenance organization, group medical practice, or a medical clinic.” 35 U.S.C. § 287(c)(2)(C). The term “professional affiliation” means “staff privileges, medical staff membership, employment or contractual relationship, partnership or ownership interest,

academic appointment, or other affiliation under which a medical practitioner provides the medical activity on behalf of, or in association with, the health care entity.” *Id.* at subd.

(c)(2)(D).

1. Brain Frequency’s software license agreements do not meet the definition of a “related healthcare entity”

Relying solely on *Emtel*, Brain Frequency attempts to avoid liability by claiming that because it licenses its technology to medical providers, it has a “professional affiliation” with its licensees and is therefore a “related healthcare entity.” Brain Frequency’s superficial analysis is overly simplistic and attempts to expand application of the physician’s immunity from its statutory (and limited) scope to apply to anyone with a contract with a medical practitioner, regardless of the scope or nature of the contract.

Emtel does not hold that *any* contractual relationship is sufficient to define a “related healthcare entity.” Instead, it attempts to strike a balance between agreements for the direct provision of medical services, which are immune, and those where a physician “merely agree[s] to use the movants’ services or property in medical practice,” which are not immune. *Emtel*, 583 F. Supp. 2d at 824-825.

The distinction, the *Emtel* court explained, was that the purpose of the moving parties’ agreements was to have its network of independent contractor physicians provide direct medical assistance to other physicians’ patients. *Id.* at 825 (“the agreements call for the movants to match a request for medical assistance from a remote medical facility with an affiliated physician who has a particular responsive specialty, and for that physician to use videoconferencing to view a patient who is located in the remote facility and provide medical services to that patient.”)

Brain Frequency’s license agreements with its customers fall in the latter, non-immune, category of contracts merely for the use of services or property in a medical practice. Unlike the

movants in *Emtel*, Brain Frequency does not perform *any* medical activities or administer patient treatments. As stated in its contract *twice*:

NEITHER BRAIN FREQUENCY NOR THE BRAIN FREQUENCY SYSTEM PROVIDES MEDICAL ADVICE, INSTRUCTION FOR DIAGNOSIS OF A MEDICAL CONDITION, OR INSTRUCTION FOR TREATMENT OF A MEDICAL CONDITION.

Doc. 30-8⁵ at 1, 10 (emphasis original).

As Brain Frequency admits, it was created solely to house and license software. Doc. 30-3 (Manish Decl.) ¶ 4 (Brain Frequency provides software technology...); ¶ 6 (“Brain Frequency license the Brain Frequency Software to a total of five individual medical practitioners...”). The medical providers, not Brain Frequency, provide the medical treatments. *Id.* ¶ 8 (“Each of Brain Frequency’s medical practitioner licensees provide medical diagnosis or treatment...”); ¶ 10 (“Brain Frequency only provides software to assist in the facilitation of treatments...”).

Brain Frequency’s business of commercially licensing patented technology to third parties is easily distinguished from the practices of the “related health care entities” in *Lamson* and *Emtel*. In *Lamson*, the plaintiff did not dispute that Section 287(c) covered the defendant’s activities, but argued only that the defendant, the federal government, was not permitted to avail itself of Section 287(c)’s protections (an argument the court rejected). 117 Fed. Cl. at 757. In that case, the government employed medical professionals who used virtual reality methods to treat military personnel. *Id.* at 756-57. In contrast, as noted above, Brain Frequency admits that it is not directly involved in any performance of medical activities for its licensees.

Brain Frequency attempts to distort *Emtel* claiming that “[e]ven though movants did *not* provide the actual medical treatment or diagnosis themselves, their agreements and relationships

⁵ Exemplar “Brain Frequency System License and Services Agreement”, Exhibit 5 to Manish Decl. See Doc. 30-8 (Manish Decl.) ¶ 7.

with independent contractor physicians qualified them as ‘related healthcare entities.’” Doc. 30 at 9 (citing *Emtel*, 583 F. Supp. 2d. at 824-825). Brain Frequency’s argument, however, omits critical facts. In *Emtel*, the “related healthcare entities” “agree[d] to provide outsourced medical diagnosis or treatment from affiliated physicians” through real time video conferencing software, allowing remote physicians “to view a patient . . . and provide medical services to that patient.” 583 F. Supp. 2d at 824-25. In other words, the doctors were treating patients in the same manner as if they were in person, but via video conference. In this circumstance, the court held that the video conference provider was a “related healthcare entity.” *Id.* at 825.

As noted above, Brain Frequency admits it does not diagnose patients and does not provide treatments, either directly or indirectly, to patients. In fact, its contracts with its licensees expressly disavow *any* such medical activity, as they must since Ms. Manish is not a doctor. Instead, Brain Frequency’s contracts are limited to licensing its infringing technology to doctors. Thus, Brain Frequency cannot be a “related healthcare entity.”

2. Brain Frequency is not a medical facility

Brain Frequency is also not a “related healthcare entity” for a second, separate reason: it is not a healthcare facility at which the medical activity is performed. The definition of “related healthcare entity” provides specific examples of the types of entities it is intended to cover: “a nursing home, hospital, university, medical school, health maintenance organization, group medical practice, or a medical clinic.” 35 U.S.C. § 287(c)(2)(C).

While this list is not exhaustive, it is a principle of statutory construction that, “where general words follow specific words in a statutory enumeration, the general words are construed to embrace only objects similar to those enumerated by the specific words.” *Wash. State Dept.*

of Soc. and Health Servs. v. Guardianship Estate of Keffeler, 537 U.S. 371, 372 (2003).⁶ Here, the list of examples demonstrates that Section 287(c) is intended to protect medical facilities at which medical providers perform their work, not companies like Brain Frequency that merely provide technologies to those providers and facilities.

This is consistent with the legislative history of Section 287. As Senator Bill Frist, who was instrumental in drafting and passing the legislation explained: “My legislation is very narrow in scope. It would simply prevent the enforcement of patents against health professional *or their affiliated facilities* for pure procedure patents such as Dr. Pallin’s.” *Emtel*, 583 F. Supp. 2d at 822 (quoting 142 Cong. Rec. 12023–01, 1996 WL 553950 (statement of Sen. Frist) (emphasis added)). Congress again described the related healthcare entities defined in Section 287(c) as “facilities” in discussions related to an associated bill. *See Background and Issues Relating To the Patenting of Tax Advice Scheduled For A Public Hearing Before the Subcommittee On Select Revenue Measures of the House Committee On Ways and Means On July 13, 2006*, 2006 WL 4791664, at *9 (“Under this statute, a patent holder generally cannot obtain either damages or injunctive relief against a licensed medical practitioner or *related health care facility* with respect to the performance of a medical activity that constitutes an infringement of the patent.” (Emphasis added).)

The statutory protection applies only for a medical procedure on the human body (or on an organ or cadaver, or a nonhuman animal used in medical research or instruction directly relating to the treatment of humans) which does not involve the use of a patented machine,

⁶ While the court in *Emtel* rejected plaintiff’s statutory construction analysis, it was clear in that case that the defendant entities were providing, based on explicit provisions in their contracts, remote medical services directly to patients (as if they were in person), which Brain Frequency does not provide or perform here. *See Emtel*, 583 F. Supp. 2d at 284-825 (finding that “[i]n the agreements with the medical care facilities the [defendants] agree to provide outsourced medical diagnosis or treatment from affiliated physicians”).

patented matter, or a valid biotechnology patent. Therefore, while it is possible to obtain a patent on a medical procedure falling within the scope of the statute (such as a novel surgical technique), the patent holder generally will be unable to enforce such a patent against a licensed medical practitioner or *related health care facility*.”).

Put a different way, “the provision immunizes the practitioner and *the institutions they work for* from all liability for infringement in connection with medical treatment.” *Lamson*, 117 Fed. Cl. at 762. Brain Frequency is not a facility at which a physician performs a TMS treatment, nor is Brain Frequency an institution for which its licensees work. Brain Frequency is simply a service provider. Again, Brain Frequency simply is not a “related healthcare entity.”

C. Brain Frequency’s Infringement of the Asserted Method Claims Includes Its Commercialization of a Regulated Medical Device

Even if Brain Frequency were a “related healthcare entity,” it still lacks immunity under Section 287(c)(3), which provides:

This subsection does not apply to the activities of any person, or employee or agent of such person (regardless of whether such person is a tax exempt organization under section 501(c) of the Internal Revenue Code), who is engaged in the commercial development, manufacture, sale, importation, or distribution of a machine, manufacture, or composition of matter or the provision of pharmacy or clinical laboratory services (other than clinical laboratory services provided in a physician's office), where such activities are:

- (A) directly related to the commercial development, manufacture, sale, importation, or distribution of a machine, manufacture, or composition of matter or the provision of pharmacy or clinical laboratory services (other than clinical laboratory services provided in a physician's office), and
- (B) regulated under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or the Clinical Laboratories Improvement Act.

35 U.S.C. § 287(c)(3).

While Brain Frequency attempts to evade this express exemption to its potential immunity by claiming that it only licenses software, Brain Frequency admits that its software *requires* the use of a TMS device to function. Doc. 30-8 at 4 (exemplar license agreement § 2.2

Conditions of Use require “Licensee must acquire the equipment listed on Schedule 2 for the operation of the Brain Frequency System.”); *id.* at 14 (Schedule 2 listing a MagVenture MagPro R30-PR TMS device as required equipment.); Mallgrave Decl. ¶ 5 (statement on Brain Frequency website, under “treatment process,” stating “Brain Frequency treatments will begin, **using FDA Approved equipment**, in a calm and safe setting.” (Emphasis added)). In other words, Brain Frequency’s licensed software is designed to work, and *can only work* as an integrated system with a “Brain Frequency approved TMS Treatment Machine.” Doc. 30-8 at 14.

Not only does Brain Frequency software require its “approved” TMS machine to work, but Brain Frequency itself offers to lease the required device to its licensees. Ms. Malish’s claims to the contrary, that Brain Frequency “does not provide or sell TMS or EEG devices,” (Doc. 30-3 ¶ 10), are belied by Brain Frequency’s own contract. The contract, attached to Ms. Malish’s declaration, repeatedly references Brain Frequency’s ability to lease the “approved” equipment directly to its customers.⁷ Doc. 30-8 at 1 (§ 1.7 defining “Lease Fees” as “the fees for lease of any equipment that may be set forth in Schedule 2”); *id.* at 4 (§ 2.2.2 “If Schedule 2 states that Licensee will lease the equipment from Brain Frequency, then the terms of this Agreement will apply to such lease.”); *id.* at 5 (§ 4.3 “Licensee shall properly handle and maintain all equipment that Licensee leases from Brain Frequency.”); *id.* at 7 (§ 5.13 “Lease Fees will be due prior to the start of the applicable lease period.”); *id.* at 8 (§ 6.3 upon termination (“Licensee shall return to Brain Frequency all equipment that it has leased from Brain Frequency”).

Ms. Malish also falsely states that Brain Frequency does not “make, sell, or offer to sell,

⁷ This alone creates a genuine issue of material fact requiring the denial of Brain Frequency’s Motion.

or market any products regulated by the Food and Drug Administration.” Doc. 30-3 ¶ 12.

Again, Brain Frequency’s own contract demonstrates that it “sell[s], offer[s] to sell, or market[s]” the MagVenture TMS device as a “Brain Frequency approved TMS Treatment Machine.” The MagVenture TMS device, unquestionably, is regulated under the Federal Food, Drug, and Cosmetic Act. *See* RJN, Exs. A-H.

Brain Frequency’s actions also are directly related to commercializing its product. Brain Frequency not only leases its “approved” TMS device, but promotes the use of that same device, with its software, on at least one podcast (the “Gladden Longevity Podcast”) and through Spotify. Mallgrave Decl. ¶ 3, Ex. I. Despite Ms. Malish’s self-serving statement that her appearance on the “Gladden Longevity Podcast” in November 2022 was to provide “educational information” to medical providers, her appearance constitutes undeniable product promotion. In *Viveve, Inc. v. Thermigen, LLC*, No. 2:16-CV-1189-JRG, 2017 WL 1425604 (E.D. Tex. Apr. 20, 2017), the court rejected the same argument that an appearance on a television show was “to inform the public about medical procedures”, holding instead that the defendant doctor’s media appearance was “directed to one purpose: product promotion...devoted to extolling the virtues of [the product he sold] and [was] much closer to an advertisement than a medical lecture.” *Id.* at *4. Similarly, rather than discussing the science behind Brain Frequency’s software, during her podcast appearance, Ms. Malish discusses the Brain Frequency System at a colloquial level aimed to promote the benefits of her product. For example, Ms. Malish refers to Brain Frequency as giving patients a “tune up” to their brain and how she personally plans to get one every few years when she reaches the age of 60.

<https://open.spotify.com/episode/1tYFdD61I7dN4nvD7YrKKK?si=ef34fadb30054a80&nd=1&dlsi=069aab8dd96a4b38> (last visited May 17, 2024 at 43:20-43:42.)

Lest there be any confusion about the commercial nature of Ms. Malish’s appearance, in conjunction with that podcast, Brain Frequency offered, and continues to offer, a *discount* for podcast listeners “at all affiliate sites” that are “located on the website” at <https://brainfrequency.ai/>. Mallgrave Decl. ¶ 3, Ex. I. Not coincidentally, Dr. Jeffrey Gladden, the host of the Gladden Longevity Podcast, and his company, Gladden Longevity, are Brain Frequency providers (licensees) and featured prominently on Brain Frequency’s website. Mallgrave Decl. ¶ 4; <https://brainfrequency.ai/texas> (last visited May 17, 2024).

Thus, Brain Frequency is directly engaged in the “commercial sale...or distribution of a machine” that is “regulated under the Federal Food, Drug, and Cosmetic Act.” As a result, the exemption set forth in Section 287(c)(3) applies, and Brain Frequency is not immune from liability for patent infringement.

V. IN THE ALTERNATIVE, WAVE REQUESTS ADDITIONAL TIME TO CONDUCT DISCOVERY

In the alternative to denying Brian Frequency’s Motion, Wave requests time to conduct discovery to obtain additional facts to refute Brain Frequency’s alleged undisputed facts. Pursuant to Federal Rule of Civil Procedure 56(d), if a nonmovant shows by affidavit or declaration that “it cannot present facts essential to justify its opposition,” the court has the discretion to defer consideration of the motion and allow time for discovery. Fed. R. Civ. P. 56; *see also Wichita Falls Off. Assocs. v. Banc One Corp.*, 978 F.2d 915, 919 (5th Cir. 1992) (to trigger this rule “non-movants need only submit an equivalent statement preferably in writing that conveys the need for additional discovery”) (citation omitted). Rule 56(d) (formerly denominated as Rule 56(f)) requests are “generally favored and should be liberally granted.” *Stearns Airport Equip. Co. v. FMC Corp.*, 170 F.3d 518, 535 (5th Cir.1999).

Here, as identified in the Declaration of Deborah S. Mallgrave, the parties have yet to engage in any meaningful discovery. Mallgrave Decl. ¶ 6. Wave propounded requests for production of documents to Brain Frequency, but Brain Frequency has yet to produce any documents. *Id.* Nor have the parties begun taking depositions. *Id.* Specific to this Motion, discovery could reveal additional facts related to Brain Frequency’s business, the relationship between Brain Frequency and its customers and licensees, Brain Frequency’s lack of engagement in medical activities, and Brain Frequency’s commercialization of its software and the “approved” MagVenture TMS device it requires its licensees to use.

Accordingly, as an alternative to denying the Motion, the Court should defer its decision to permit Wave additional time to conduct discovery and supplement its response to the Motion.⁸

VI. CONCLUSION

For the foregoing reasons, Wave respectfully requests that the Court deny Brain Frequency’s Motion for Partial Summary Judgment, or in the alternative, defer consideration of the Motion to permit Wave additional time to conduct discovery and supplement its response in Opposition to the Motion.

⁸ As discovery in this case is in its infancy, Wave respectfully requests that any continuance for purposes of discovery should extend through the discovery period, and that Wave be entitled to file a supplemental response two weeks after the deadline for completion of fact discovery, or on February 7, 2025.

DATED: May 17, 2024

Respectfully submitted,

/s/ Deborah S. Mallgrave

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that counsel of record who are deemed to have consented to electronic services are being served with a copy of this document via the Court's CM/ECF system per Local Rule CV-5(a) on May 17, 2024.

/s/ Deborah S. Mallgrave
Deborah S. Mallgrave